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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/402,564 01/27/00 LOUVEL

P P1047/20008

HM12/0129
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EXAMINER

PULLIAM, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

01/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/402,564

Applicant(s)

LOUVEL ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2000.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Request for Extension of Time and the Amendment A, both received December 4, 2000.

Claims 1-4 have been canceled and new claims 5 and 6 have been added.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/14058 to Ohslack *et al.* (hereinafter WO '058). WO '058 teaches a sustained release dosage form comprising a plurality of microparticles produced via melt extrusion techniques (abstract), and WO '058 also discusses the extruder used to make the formulation. WO '058 teaches that the active ingredient in the formulation is in a matrix including a hydrophobic material, such as alkylcelluloses and acrylic polymers, and a hydrophobic carrier (p 6, l 13-30). However, WO '058 further teaches that a plasticizer can also be added to help with the extrusion process (p 10, l 21-26). WO '058 also teaches a method for preparing their formulation, which involves blending the drug with the matrix ingredients, heating the blended mixture, placing the mixture in the extruder, extruding the strands, then dividing the strands into the desired pieces, such as pellets (p 7, l 15-30, and claim 18). WO '058 also teaches that the extruded materials can be cut into multiparticulates by any means known in the art, and they further teach that the

Art Unit: 1615

multiparticulates can be compressed into tablets (p 8, l 1-2). Lastly, WO '058 teaches that the exit port of the extruder can be any desired shape, in order to make the multiparticulates the desired shape and size (p 17, l 23-25). It is the position of the examiner that this disclosure reads on the method of making particles as claimed by applicant.

Claim Rejections - 35 USC § 103

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WP 96/14058 to Oshlack *et al* as applied to these claims above. Although WO '058 does not teach that the particles are spheroidal, they do teach that the exit port of the extruder can be any shape desired. They further teach that they want to eliminate the spheronization step, which is stated by applicant as well, and it is the position of the examiner that by allowing the exit port of the extruder to be any shape so that the multiparticulates can be of any shape, this allows the exit port to be a shape that would form spheroidal particulates. In addition, applicant states that the particles are preferably spheroidal, which does not necessarily require that they be spheroidal. Further, although WO '058 does not specifically refer to a maturing step, it is the position of the examiner that the heating step prior to extrusion, which is discussed by WO '058, reads on applicant's claimed maturing step. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments filed December 4, 2000 have been fully considered but are not found persuasive. Applicant argues that the heating step relied upon in WO '058 does not teach the maturing step of applicant's claimed process. However, the examiner respectfully disagrees. WO '058 does teach a heating step prior to the extrusion, and applicant's claimed maturing step is simply a heating step with a defined time and temperature. There is no evidence that the prior art heating step is different than applicant's, nor is there any evidence that there is a patentable difference between the resulting products. Therefore, this rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Application/Control Number: 09/402,564
Art Unit: 1615

Page 5

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam
Patent Examiner
Art Unit 1615
January 23, 2001

THURMAN K. PAGE
PATENT EXAMINER
JAN 23 2001
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